

REMARKS

Claims 1 and 2 are pending in this application. Claim 1 has been amended to delete the recitation “an animal or” and to include the limitation “wherein said viral disease is human immunodeficiency virus” contained in claim 3. Claims 3-5 have been canceled. No new matter has been added. In view of the foregoing amendments and the following remarks, Applicant believes that the asserted rejections should be withdrawn and that pending claims 1 and 2 are in condition for allowance.

The specification of the instant application has been amended to update the status of the parent cases.

35 U.S.C. § 112 Rejections

Claims 1-5 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner asserts that the recitation “administering at least one effective dose” is vague and indefinite.

Applicant respectfully points out that it is clear from Nagaoka III (JP 58107159, entitled “Preparation of Health Drink”), which disclosure predates the filing date of the instant application, that the extract administered according to the claimed invention is a “healthy drink.” Thus, it would be clear to one skilled in the art what dosage amount of the extract of the claimed invention to use in an orally consumed health drink. Additionally, other dosage issues, such as toxicity, would be understood by one skilled in the art not to be relevant with respect to a health drink. Applicant respectfully requests, therefore, that this ground for rejection be withdrawn.

Claims 1-5 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that, while the specification is enabling for the *in vitro* treatment of viruses such as human immunodeficiency virus (HIV), it is not enabling for the *in vivo* treatment of all viral diseases.

The present invention as now claimed is directed to a *Lentinus edodes* mycelium extract administered to a human afflicted with HIV to treat the HIV infection. Applicant points out that the specification makes clear that the preparation of the claimed extract has been known prior to the filing of the instant application. Thus, one skilled in the art would already know how to make the extract and to administer it as a healthy drink. Therefore, Applicant submits that one

skilled in the art would be able to determine in a reasonable number of tries how to administer the extract to a human afflicted with HIV.

With respect to the Examiner's assertions that *Lentinus edodes* strains are not disclosed in the specification, Applicant points out that all strains of *Lentinus edodes* may be used in the claimed invention, and thus there is no need to specify any particular *Lentinus edodes* strain. To corroborate this point, Applicant attaches herewith an expert's Declaration dated May 11, 1998, previously submitted and made of record in parent application 08/519,293. In the Declaration, the declarant attests, in Paragraph 7, that "any strain of the fungus Lentinus edodes is suitable for use in practicing the claimed invention. My prior Declaration [dated June 9, 1997] reported results achieved using one strain of Lentinus edodes, and that strain is exemplary of all strains of Lentinus edodes. The anti-HIV efficacy of an extract produced according to the present invention is essentially unaffected by the strain of Lentinus edodes." Based on the foregoing, Applicant submits that the specification is more than reasonably enabled for one skilled in the art to practice the present invention as now claimed without undue experimentation.

35 U.S.C. § 103 Rejection

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) for asserted obviousness over Amagasse in view of Nagaoka III.

Applicant respectfully traverses this rejection and requests that the rejection be reconsidered and withdrawn.

As discussed above, the present invention as now claimed is directed to a *Lentinus edodes* mycelium extract administered to a human afflicted with HIV to treat the HIV infection. In contrast, Amagasse discloses a method of treating hepatitis B infection using an extract of *Lentinus edodes*. Applicant points out that Amagasse is silent with respect to using its extract to treat HIV infection. Applicant further points out that, unlike HIV, which is a retrovirus, hepatitis B is not a retrovirus, and thus one skilled in the art would not be motivated to use the Amagasse extract to treat HIV infection. Applicant, therefore, submits that the possibility of the mycelium extract disclosed in Amagasse being useful to treat HIV would have been speculative at best until substantiated by Applicant's test results as presented in parent application 08/519,293 and corroborated in two expert's Declarations, dated October 4, 1995 (hereinafter "the '95

Declaration”) and June 9, 1997 (hereinafter “the ’97 Declaration”), respectively, attached herewith, previously submitted and made of record in the 08/519,293 application. A brief summary of the ’95 and ’97 Declarations follows.

In the ’95 Declaration, the declarant attests, in Paragraph 3, that Experiments I and II were carried out in order to support the unexpected results obtained from the extract of the present invention with respect to its efficacy to treat HIV. In particular, the anti-HIV effect of two comparative samples of a *Lentinus edodes* extract, A and B, prepared as described in Paragraph 3 of the ’95 Declaration, were investigated in Experiments I and II, respectively, and then compared to the anti-HIV effect of the *Lentinus edodes* extract composition of the claimed invention. All samples were measured in accordance with the method described in “Antiviral Research,” Vol. 20, pp. 317-331 (1993). The results of Experiments I and II are shown in Tables A and B in Paragraph 3 of the Declaration. When the concentration of samples A and B were 125 µg/ml, the viability of the HIV-infected MT-4 cells were as low as 10.7% and 35.0%, respectively. By contrast, when the concentration of the pharmaceutical composition extract for inhibiting HIV of the claimed invention was 125 µg/ml, the viability of the HIV-infected MT-4 cells was as high as 71.5%.

Additionally, as attested to by the declarant in the ’97 Declaration in Paragraph 3, Experiments I, II and III were carried out to further support the unexpected results obtained from the *Lentinus edodes* extract of the claimed invention. In particular, two comparative samples, 1 and 2, were prepared as described in Paragraph 3 of the Declaration in Experiments I and II, respectively. The results for Samples 1 and 2 are shown in Tables A and B, respectively. In Experiment III, the *Lentinus edodes* mycelium extract of the claimed invention was prepared in the same manner as provided in Preparation Example 1 of the parent application 08/519,293, with the exception that the purified cellulase was changed from 2 g to 5 g. The results from Experiment III are shown in Table C. All samples were measured in accordance with the method described in “Antiviral Research,” Vol. 20, pp. 317-331 (1993).

The results demonstrate that when the concentration of Sample 1 is 125 µg/ml, the viability of the HIV-infected MT-4 cells is as low as 25.1%. In contrast, in Samples 2 and 3 (incorrectly stated in the Declaration as Samples 1 and 2), when the concentration of the

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pharmaceutical *Lentinus edodes* mycelium extract of the claimed invention is 125 µg/ml, the viability of the HIV-infected MT-4 cells is as high as 70.0% and 70.8%, respectively.

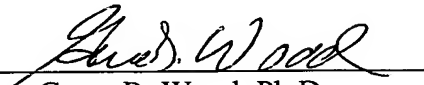
Thus, both the '95 and the '97 Declarations provide evidence that the pharmaceutical *Lentinus edodes* mycelium extract of the claimed invention demonstrates new and unexpected efficacy with respect to anti-HIV activity.

Applicant respectfully submits that neither Amagasse nor Nagaoka III, either alone or in combination, teaches or suggests the new and unexpected finding of the claimed invention, namely, that the pharmaceutical *Lentinus edodes* mycelium extract is efficacious against HIV infection.

In view of the foregoing remarks, it is respectfully submitted that pending claims 1 and 2 in the present application comply with the requirements of Section 112 and are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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